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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,562	BRAUN ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10,11,14-16,19-29,35-40 and 47-68* is/are pending in the application.

4a) Of the above claim(s) *1-5,10,11,14-16,19-29,35 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *36-40 and 47-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment submitted 17 January 2006 has been entered. Claims 1-5, 10-11, 14-16, 19-29, 35 and 68 have been withdrawn. Claims 6-9, 12-13, 17-18, 30-34 and 41-46 have been cancelled. Claims 67-68 are new. Claims 1-5, 10-11, 14-16, 19-29, 35-40 and 47-68 are currently pending in this application.

Withdrawn Rejections

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn, except the rejection of claim 36 which remains indefinite due to lack of correlation between the preamble and body of the claim.

Election/Restrictions

1. Newly submitted claim 68 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of a) claims 36-40 and 47-67 and b) claim 68 are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of groups a and b do not overlap in scope, are not obvious variants and have materially different modes of operation. The process of group a requires employing information fusion to process a biological response, which is not required of the process of group b. The process of group b requires applying biological data to train a machine, which is not required of the process of group a.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 68 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

2. The Delehanty et al. reference included on the information disclosure statement (IDS) submitted on 5 August 2004 was not previously considered because no copy of the reference was provided. The reference has now been considered as indicated on the IDS enclosed. Previously considered references are indicated with a strike-through.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 36-40 and 47-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 lacks correlation because the preamble of the claim recites a method for identifying a pathogenic agent, but the method steps appear to merely employ information fusion to process a biological response to identify a pathogenic agent. Although the claim recites the information fusion process being employed to identify a pathogenic agent. It is unclear whether the pathogenic agent is actually identified, or whether the claim is merely intended to employ information fusion. If identification of a pathogen agent is required the claim must recite a separate method step specifying identification of a pathogenic agent. Claim 36 further recites "a

pathogenic agent" in line 6 of the claim. It is unclear whether the "a pathogenic agent" is the same pathogenic agent recited in the preamble of the claim and the pathogenic agent of which the biological data is representative.

Claim Rejections - 35 USC § 102

1. Claims 36-38, 40 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Manger et al. (How the host 'sees' pathogens: global gene expression responses to infection, Current Opinion in Immunology, 2000, Vol. 12, pages 215-218).

Manger et al. teach a method for identifying the presence of a pathogenic agent, comprising: collecting disparate types of biological data representative of a biological response to the same pathogenic agent (comparing responses induced by sets of microorganisms that differ, pg. 217, left column, second paragraph, lines 1-5), and employing information fusion to process the biological response (examined wide variety of species and applied two-way clustering across genes, collect and analyze response profiles obtained from human cells is employing fusion in order to determine biological responses, pg. 217, left column, second paragraph last 2 lines-right column, first paragraph) to identify a pathogenic agent (pathogen recognition is utilized, pg. 218, right column).

Regarding claims 37 and 38, Manger et al. teach collecting multiple modalities of biological data representative of a biological response to a pathogenic agent (diagnostic signatures are collected for different genes with the same pathogen, pg. 217, left column, second paragraph). Manger et al. teach collecting data including employing at least one microarray each having at least one set of probes (DNA microarrays are used to view the transcription events that underlie the host response to pathogens (pg. 215, right column, second paragraph, lines 1-3;

microarrays are used to examine responses from a large number of genes, pg. 216, left column, second paragraph). Manger et al. also teach the biological response including the biological response of a host cell (response from human cells exposed to infectious agents, which are pathogens, pg. 217, left column, second paragraph, last 2 lines-right column, first paragraph, host cell, pg. 215, third paragraph, lines 6-10).

With respect to claim 67, Manger et al. teach the pathogenic agent being uncataloged (pathogenic agent is unknown prior to identification, pg. 217, left column last paragraph-right column).

2. Claims 36, 39, 47-51, 53-55 and 58-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhu et al. (US 2004/0014027).

Zhu et al. teach a method for identifying the presence of a pathogenic agent comprising: collecting disparate types of biological data representative of a biological response to the same pathogenic agent (different sets of arrays creates a control and disparate types of data are collected from the arrays, par. 0138), and employing information fusion to process the biological response (information from test sample and control sample are fused, par. 0114) to identify a pathogenic agent (expression levels of genes that are induced or repressed by HCMV are identified to provide identification of HCMV, par. 36; pathogen signature is measured, par. 135).

With respect to claims 39 and 47-49, Zhu et al. teach collecting disparate types of biological data comprising: providing a set of host cells and contacting the cells with the pathogenic agent or any sample containing pathogenic agent (par. 0130, 0136), employing a microarray having a plurality of probes to measure a plurality of biological responses of the host cells (par. 0135), and wherein the method further includes, applying the plurality of biological

responses of the host cells to train a machine learning system to recognize the pathogenic agent (control sample results compared with test sample results, par. 0114), and detecting an identifying the pathogenic agent in a sample (par. 0138), by exposing host cells to the sample (par. 0130, 0136), using a microarray to measure plural biological responses provoked in host cells (par. 0135), and employing the trained machine learning system to identify the pathogenic agent (par. 0114). Zhu et al. further teach employing the set of host cells and a plurality of microarrays to increase a plurality of biological responses (four microarrays employed, par. 0135), and applying machine learning processes to the plural biological responses to identify a pathogenic signature (control signature obtained to analyze test signature, par. 0114). Zhu et al. further teach providing a plurality of sets of host cells (repeated multiple times, which means multiple sets of were used, par. 0130, 0136), contacting the host cells with a sample containing pathogenic agents to provoke and measure a plurality of biological responses (pathogens are contacted with plurality of host cells, therefore plurality of responses are generated, par. 0136), training a recognizer to detect one or more of the pathogenic signatures in a biological response provoked in a host cell (computer is trained to recognize the signature for the control sample, par. 0114), and applying machine learning to at least one pathogenic signature (signature from control sample is compared with signature from test sample, par. 0114).

With respect to claims 50 and 51, Zhu et al. teach employing substantially all of the measured biological response data during the identification method to widen the scope of information employed during pathogen detection and including identifying a pathogen signature having substantially all of the measured biological data (par. 0135).

Regarding claim 53, Zhu et al. teach using the host cells as a natural amplification mechanism, thereby allowing improved detection and identification of pathogenic agents (par. 0038 and 00136).

With respect to claims 54 and 55, Zhu et al. teach employing a microarray wherein the modality is genomic (par. 0080). Although the claim recites employing microarrays of different modalities, the claim recites employing a single microarray and not a plurality of microarrays. Therefore, the claim is interpreted as employing a single microarray with a single modality.

Regarding claims 58 and 59, Zhu et al. teach fusing information from multiple microarray types (control and test microarrays, par. 0114) and fusing multiple candidate identification responses generated by multiple classifiers (control and test samples for mock-HCMV and HMCV, par. 0114, 0136, 0138).

Claim Rejections - 35 USC § 103

3. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manger et al., as applied to claim 36, in view of Brown et al. (Knowledge-based analysis of microarray gene expression data by using support vector machines, PNAS, 2000, pages 262-267).

Manger et al., as applied to claim 36, teach a method for identifying the presence of a pathogenic agent, but fail to teach applying machine learning.

Brown et al. teach applying machine learning to process the biological data (pg. 262, left column, 3rd paragraph) and to develop a signature for the pathogen that includes substantially all of the data collected by common probes among the microarrays (signatures for class definitions are created, pg. 263, right column, 5th paragraph), in order to functionally classify genes by using gene expression data from DNA microarrays.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Manger et al., applying machine learning as taught by Brown et al., in order to provide superior gene recognition by producing less false positive and false negative results.

4. Claims 52 and 60-66 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (US 2004/0014027) in view of Braun (Sensor Data Fusion with Support Vector Machine Techniques, 2002, Sensor Fusion: Architectures, Algorithms, and Applications VI, pages 98-109) further in view of Brown et al. (Knowledge-based analysis of microarray gene expression data by using support vector machines, 2000, PNAS, pages 262-267).

Zhu et al., as applied to claim 47, teach a method of collecting disparate types of biological data representative of a biological response, but fail to teach partitioning an input space of microarray probes.

Braun teaches using a support vector technique to partition an input space into one or more computation subspaces (pg. 101, second paragraph) and generate measures of fitness for the subspaces (computing the incompleteness for the subspaces, pg. 104, second paragraph), in order to provide data incompleteness correction, but fail to teach the input space being a microarray.

Brown et al. teach using a microarray of probes (pg. 262, right column, last paragraph) and using a support vector technique (pg. 263, left column, fourth paragraph), in order specify which data should cluster together.

Therefore it would have been obvious to include in the method of Zhu et al., a support vector technique to partition an input space and generate measures of fitness as taught by Braun,

in order to provide superior gene recognition for microarrays by producing less false positive and false negative results as taught by Brown et al.

With respect to claim 52, Braun teaches allowing a recognizer to generate plural decision results (pg. 99, second paragraph), and fusing the plural decision results to generate a determination of recognition of events (pg. 99, second paragraph-third paragraph). The recognition events are the determination of pathogens in a sample in Zhu et al. and therefore the identity of a pathogen of Zhu et al. when the method of Braun is applied.

Regarding claims 61-63, Braun teaches generating multiple measures of fitness within a subspace wherein intra-subspace measures of fitness are dynamic having a value depending on the region within the subspace and position within the subspace of a point representing the test sample (dynamic incompleteness calculations are calculated, pg. 104, second paragraph). Braun also teaches determining for a subspace a fitness measure representative of effectiveness of a classifier operating in the respective subspace (constructing a classifier, pg. 100, last paragraph) and partitioning an input into a plurality of subspaces (original space divided into higher-dimensional space, pg. 101, second paragraph).

With respect to claims 64-66, Braun teaches fusing measures of recognition generated from respective areas of the subspaces (pg. 104, fifth paragraph) and using subspace measures of fitness and fusing multiple classifiers (pg. 105, last paragraph-pg. 106, first paragraph). Braun teaches applying Dempster-Shafer theory of evidence for fusing multiple classifiers (pg. 99, last paragraph).

5. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (US 2004/00140127) in view of Glezer et al. (US 2004/0189311).

Zhu et al., as applied to claim 1, teach a method for identifying the presence of a pathogenic agent of a virus, but fail to teach the pathogenic agent being a toxin.

Glezer et al. teach using arrays for detection of a pathogenic agent being a toxin or virus (par. 0296), in order to provide panels for an immunoassay.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Zhu et al., employing a microarray fro detection of a toxin as taught by Glezer et al., in order to detect potential bioterrorism agents.

Response to Arguments

6. Applicant's arguments filed 17 January 2006 have been fully considered but they are not persuasive.

7. At page 14 applicant addresses rejection of claims 36-38 and 40 under 35 USC 102(b), applicant argues that Manger et al. merely observes the way in which host cells respond to infection and fails to permit the identification of a pathogenic agent based on analysis of a pathogenic signature generated upon infection. However, in response to applicant's arguments, analysis based on a pathogenic signature is not recited in the rejected claims and is therefore not required. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. At page 14, applicant further argues that Manger does not disclose "fusion" of information and instead disclose "clustering" of information. Applicant further argues that "information fusion" is a term of art in computer science and artificial intelligence, wherein multiple sources of data are made to work together to solve a problem or perform a recognition

task. However, in response to applicant's argument, the description and definition of information fusion provided in the instant arguments is not provided in the original specification. It is noted that the original specification, at page 7, describes information fusion as a process that facilitates specific embodiments including: use of multiple types of host cells; use of cells derived from multiple organisms; side-by-side use of multiple microarrays of different probe content; use of expression modalities other than genomic. Manger et al. teach a process that facilitates the use of side-by-side multiple microarrays of different probe content, which is an information fusion process as defined by the original specification. Regarding applicant's arguments that information fusion is a term of art in computer science and artificial intelligence with a well-known definition, mere allegation that a term is a "term of art" or a definition of a term that is not provided in the original specification is not sufficient to provide description for a previously undefined term. Furthermore, applicant does not provide a dictionary definition for "information fusion" in the instant arguments or the original specification. Therefore, applicant's definition in the instant arguments is not persuasive. Applicant also argues that the ability of an exemplary information fusion technique is to enable decision-making based even on insufficient data, which differentiates it from a simplistic data comparison technique. However, such a limitation is not recited in the rejected claims, and is therefore not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. At page 15, applicant addresses rejections of claims 36, 47-51, 53-55 and 58-59 under 35 USC 102(e), applicant argues that Zhu et al. do not disclose "fusion" of information, and instead disclose a "comparison" of information for a test sample with information from a control sample.

Applicant's argue that information fusion involves combining multiple sources of data and making them work together to solve a problem or perform a recognition task. Applicant's arguments are not persuasive to overcome the rejection under Zhu et al. because the comparison of control and test samples of Zhu et al. are multiple data sources which are combined to perform a recognition task. Applicant further argues that "information fusion" is a term of art in computer science and artificial intelligence, wherein multiple sources of data are made to work together to solve a problem or perform a recognition task. However, in response to applicant's argument, the description and definition of information fusion provided in the instant arguments is not provided in the original specification. It is noted that the original specification, at page 7, describes information fusion as a process that facilitates specific embodiments including: use of multiple types of host cells; use of cells derived from multiple organisms; side-by-side use of multiple microarrays of different probe content; use of expression modalities other than genomic. Zhu et al. teach a process that facilitates the use of side-by-side multiple microarrays of different probe content, which is an information fusion process as defined by the original specification. Regarding applicant's arguments that information fusion is a term of art in computer science and artificial intelligence with a well-known definition, mere allegation that a term is a "term of art" or a definition of a term that is not provided in the original specification is not sufficient to provide description for a previously undefined term. Furthermore, applicant does not provide a dictionary definition for "information fusion" in the instant arguments or the original specification. Therefore, applicant's definition in the instant arguments is not persuasive. Applicant also argues that the ability of an exemplary information fusion technique is to enable decision-making based even on insufficient data, which differentiates it from a simplistic data

comparison technique. However, such a limitation is not recited in the rejected claims, and is therefore not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. At page 16, applicant further argues that Zhu et al. fail to teach a step of applying machine learning processes to a plurality of biological responses to identify a pathogenic signature. Applicant argues that "machine learning" is a term of art in computer science and artificial intelligence that involves automatic learning from data and machine learning typically includes a method by which a computer can create and modify the system's operation by processing data. Applicant further argues that machine learning consists of algorithms that learn automatically. However, in response to applicant's arguments, no such definitions are recited in the reject claims, provided in the original specification, or are dictionary definitions and are therefore insufficient to be considered valid definitions for the method of machine learning recited in the claims. Therefore, a machine learning method encompasses the recognition comparison and assignment of pathogenic signatures of Zhu et al.

11. At page 16, applicant further argues that Zhu et al. do not teach identification of the presence of a pathogenic agent. However, Zhu et al. teach identification infection caused by viruses, which are pathogenic agents.

12. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as described above, according to the original specification, Zhu et al. teach utilizing information fusion and machine learning in the context of pathogen identification and analyzing biological data. Therefore, one having ordinary skill in the art would be motivated to utilize information fusion processes as taught by Braun or Brown in order to provide superior identification of pathogenic agents. The motivation to use information fusion with multiple sets of data for superior analysis purposes is found in both references of Brown and Braun. Since multiple sets of data are analyzed in Zhu et al. it would have been obvious to use the analyses taught by Brown and Braun.

Conclusion

No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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